REMARKS

This paper is responsive to an *Official Action* that issued in this case on January 9, 2008. In that *Action*, the Office:

- Withdrew the allowance of claims 2-3, 7, 9-14, 20, 28-29, and 32-33.
- Rejected claims 1, 3-17, 21-23, and 26-34 under 35 USC §103 as being obvious over U.S. Pat. No. 4,380,439 to Kreitenburg in view of U.S. Pat. No. 7,202,851 to Cunningham *et al.*
- Rejected claims 2 and 20 under 35 USC §103 as being obvious over Kreitenburg in view of U.S. Pat. No. 6,575,757 to Leight *et al.*
- Rejected claims 18-19 and 24-25 under 35 USC §103 as being obvious over Kreitenburg in view of Cunningham *et al.* and further in view of U.S. Pat. No. 6,470,302 to Cunningham *et al.*

No claims have been amended; claims 1-34 are pending. Reconsideration is requested in view of the following comments.

I. Discussion of the Cited Art

(A) *U.S. Pat. No. 4,380,439 to Kreitenburg*

Kreitenberg discloses a neck venous and arterial examination teaching instrument. The instrument includes two basic mechanisms; one pertaining to venous flow (FIG. 2) and one pertaining to arterial flow (FIG. 3). FIG. 1 depicts the complete instrument, wherein the venous flow mechanism appears on the left side of the FIG. 1 and the arterial flow mechanism appears on the right side of the Figure.

Each mechanism comprises a cam assembly that Kreitenberg uses to simulate the "pulse waves" of venous and arterial flow. In particular, as depicted in FIG. 2 and described in accompanying text, venous cam assembly (28) includes cam (68) and vein tube (72). The vein tube is filled with a viscous fluid. The cam has a specially contoured peripheral surface or edge that is intended to reproduce the pulsations of the jugular vein.

More specifically, the contour of edge is impressed upon the vein tube via a cam-follower arrangement that includes press bar (78). That is, bar (78) reacts to the contoured edge by moving, which movement causes pulsations in vein tube (72).

Most of vein tube (72) is physically inaccessible below transparent plastic cover (12) of the instrument. A portion (86) of the vein tube is disposed on the exterior of the

cover by passing it through openings (88). According to Kreitenberg, the exposed portion (86) permits viewing of the pulsations within the tube. It is NOT to be touched or palpated by a trainee.

The arterial pulsation simulation mechanism, which includes arterial cam assembly (24) and is best shown in FIG. 3, is arranged and used somewhat differently than the venous mechanism. In particular, regarding use, a trainee is meant to actually "feel" the arterial "pulsations," whereas the venous mechanism is intended only for viewing, not touching.

Notwithstanding the fact that a trainee is intended to engage the arterial mechanism to experience tactile sensations, a pseudo artery or "arterial" tube is not used in the mechanism. Rather, the edge (94) of cam (92) bears upon overlying resilient membrane (96). The membrane is mounted over an opening in the cover (12). As the cam is rotated, membrane (96) rises and falls consistent with the contours of edge (94) of the cam. The contouring is meant to simulate either normal or pathological conditions. A trainee with several fingers placed on the membrane will sense the "up and down" movement of the membrane and the frequency of such "pulsations."

(B) *U.S. Pat. No. 7,202,851 to Cunningham et al.*

Cunningham '851 discloses a haptic interface for palpation simulation. As depicted in FIG. 1 of that reference, the simulator comprises display (105), controller (125) and haptic interface (140). The haptic interface (140) includes actuator (135) and user object (130).

Cunningham '851 discloses that the haptic interface (140) is a "tactile mouse" (200), (250), (250'), (250"), such as is depicted in FIGs. 5-9. The tactile mouse comprises what is essentially a standard mouse (*e.g.*, item (130) in FIG. 11A) that is coupled to a sensing/actuation mechanism (*e.g.*, item (135) in FIG. 11A). The sensing/actuation mechanism is capable of generating forces on the mouse. The forces that are imparted to the mouse are experienced as haptic sensations or feedback by a user.

In operation, a user moves the mouse to position the cursor at a particular location on an anatomy (*e.g.*, human arm, *etc.*) that is generated in display (105). That particular location might be representative of a region of the anatomy at which the

trainee is to palpate or otherwise explore features of a patient. Under the direction of controller (125), the sensing/actuation mechanism moves and generates forces on the mouse. The forces are meant to be indicative, to some extent, of where on the anatomy the cursor is positioned (*e.g.*, vibrations that are meant to simulate "percussion," tactile sensations that are meant to indicate the presence of internal features, *etc.*). The forces that are imparted to the mouse are thus experienced by a trainee that is using the mouse to position the cursor.

FIGs. 10, 11A, and 11B depict increasing detail of one implementation of the tactile mouse. FIG. 10 depicts the full system, showing the tactile mouse connected to the display. FIG. 11A depicts further detail, showing the mouse proper coupled, via mechanical interface (430), to transducer assembly (440) that senses the position of the mouse in its workspace and generates the forces that are imparted to the mouse and, ultimately, to the user. FIG. 11B depicts further details of the mechanical interface (430) and transducer assembly (440).

(C) *U.S. Pat. No. 6,575,757 to Leight et al.*

Leight discloses a computer-based system for physical examination training. The illustrative embodiment of Leight's system is an instrumented breast model system. The system includes a breast model (102) that overlies sensor pad (106).

The sensor pad comprises a layer of foam that has a plurality of sensors disposed therein. In the illustrative embodiment, the sensors are optical fibers. One of the fibers delivers an optical signal to a cavity within the foam. A second fiber receives the optical signal and delivers it to a photodiode. As a trainee presses down on the breast model, there will be a change in the illumination energy intensity as sensed by the photodiode. In this fashion, the pressure applied to the breast model during palpation can be sensed. (*See*, col. 5, lines 1-5; and col. 5, line 56 – col. 6, line 12.)

It is not understood how these references can reasonably be read to obviate the claimed invention. Even though the references ostensibly disclose medical trainers that in some cases can supposedly provide training in palpation techniques, none of them present an apparatus that actually permits that. We turn now to a discussion of the claims vis-à-vis the cited art.

II. Comparison of the Claimed Invention and the Cited Art

A. Rejection of claims 1, 3-17, 21-23, and 26-34 under 35 USC §103 in view of Kreitenberg and Cunningham '851

Independent claim 1 recites and apparatus comprising:

> pseudo skin; and
>
> a palpation module for enabling a user to palpate a pseudo vein, wherein said palpation module is disposed beneath said pseudo skin, and further wherein said palpation module generates a magnetic force that opposes downward motion of said pseudo vein.

The cited art does not individually or collectively "disclose" or suggest what is recited in claim 1. In particular, the cited art does not disclose a palpation module that (1) enables a user to palpate a pseudo vein nor does the cited art (2) generate a magnetic force that opposes downward motion of the pseudo vein.

One of the Office's latest mantras is something along the lines of "statements of intended use are given no weight" in determining patentability. Well, one person's statement of intended use is another person's functional limitation. The use of functional limitations is explicitly approved in the MPEP. Applicant is functionally defining the "palpation module" as something that "enable[s] a user to palpate a pseudo vein." This distinguishes it from other device, instruments, *etc.*, that are not capable of performing this function. Certain structural considerations are implicit in this functional definition. One is that there is "pseudo vein." Another is that the module must be configured so in such a way that a user must be able to "palpate" the pseudo vein.

Kreitenberg does, in fact, disclose a "pseudo vein," It is vein tube (72), which is depicted in FIG. 2. That said, the vein tube is NOT meant to be palpated or otherwise touched. It is meant to be *viewed*. On the arterial side, however, Kreitenberg discloses pseudo skin (membrane 96), but NOT an artery tube or "pseudo artery."

Rather than having a pseudo artery, Kreitenberg employs a cam that underlies the pseudo skin. The purpose of the cam is to move overlying membrane (96) to simulate pulsations. A trainee places her fingers on the membrane to learn the rhythm of the pulses, which could be indicative of a vascular problem. The trainee is

not meant to press against the membrane, palpate, or otherwise probe the membrane to feel an underlying "vein" or "artery." The action and purpose is simply to recognize the frequency and amplitude of pulsations by feeling the rise and fall of the membrane.

In summary, Kreitenberg does not enable a user to "palpate a pseudo vein." This not merely a statement of "intended use;" rather, it is a functional description of the palpation module. In other words, the module is physically adapted, configured, and arranged to permit a user to palpate a pseudo vein. A device that does enable a user to do this cannot be the basis for a rejection.

Furthermore, as recognized by the Office, Kreitenberg does not generate a magnetic force that opposes downward motion of the pseudo vein.

Regarding the claimed magnetic force, the Office alleges that:

> Note that the natural opposing force to the applied pressure ***is constant*** and it opposes downward motion of the user (opposite and equal, since the user presumably does not push the entire device into motion). There is no teaching in Kreitenburg wherein the generated force is magnetic. However, Cunningham discloses a palpation module for vascular access (among other uses) that discloses wherein the generated force can be magnetic in nature.

The Office concluded that it would have been obvious to one of ordinary skill in the art "to include magnetic feedback in the system of Kreitenberg, because the use of magnetically controlled haptic feedback is representative of the current state of the art in haptic interface simulations."

First, the statement that "the natural opposing force to the applied pressure is constant" is INCORRECT. To the extent that a user presses against membrane 96 (and it's not clear that this even occurs), the membrane would compress and naturally exhibit an constantly increasing resistance to compression. As correctly noted by the Examiner, since the entire device does not move, the "opposing force" is opposite and ***equal*** to the necessarily ***increasing*** force imparted by the user. Therefore, the natural opposing force is ***increasing***, not constant.

As emphasized in applicant's specification, when palpated "veins have a 'spongy' feel; that is, they yield to palpation pressure and do not offer any significant resistive

force." It is desirable, therefore, for a user that is palpating a pseudo vein at palpation/occlusion region 331 of haptics device 102 to experience [to] this sensation of 'yielding' or 'sponginess.'" (Para. 0063.)

Second, the fact that Cunningham discloses that actuation can rely on magnetic or electromagnetic forces provides no teaching relevant to the claimed invention. In particular, Cunningham discloses mechanism (260) including inertial mass (300) for vibrating the housing of the mouse, which vibrations are experienced by the user. The mechanism disclosed in FIG. 6 is not magnetic, but Cunningham notes that a moving-magnet actuator can be used to direct an inertial force (*i.e.*, the force generated by the inertial mass).

But this magnetic force is not used to "oppose[s] downward motion of said pseudo vein," as required in claim 1. In fact, the use of magnetic force in Cunningham has nothing to do resisting movement of anything.

Neither Cunningham nor Kreitenberg provide any suggestion whatsoever to use a magnetic force in conjunction with the movement of a pseudo vein, as recited in claim 1.

Claim 1, therefore, is not obviated by the cited art.

Independent claim 3 recites an apparatus comprising:

> pseudo skin; and
>
> a palpation module for enabling a user to palpate a pseudo vein, wherein said palpation module is disposed beneath said pseudo skin, and further wherein said palpation module ***is operable to vary a simulated stiffness of said pseudo vein***.

The Office alleges that Kreitenberg discloses all features of the claimed invention including "the stiffness (rigidity) of the vein is adjusted by the infusion of fluid. See col. 2: 20-28."

What Kreitenberg discloses in this excerpt is that "[F]or vein analysis, cam undulations cause compression in a closed flexible tube filled with fluid." Kreitenberg makes no mention of "vary[ing] a simulated stiffness of said pseudo vein." In use, the vein is filled with fluid. If it's not filled with fluid, it is not operable.

Furthermore, if Kreitenberg did vary the amount of fluid added to the vein (which he doesn't), that would vary the *actual* stiffness, not a simulated stiffness, of the pseudo vein. In illustrative embodiment of applicant's invention, the pseudo vein is embodied as molded region that comprises a solid material, such as aluminum, hard plastic, *etc*. The stiffness of applicants' pseudo vein never actually varies, what varies is the force required to press the pseudo vein down. Hence the claim language "operable to vary a simulated stiffness of said pseudo vein."

Kreitenberg provides no disclosure or suggestion to vary a simulated stiffness of the pseudo vein and, therefore, claim 3 is not obvious of that reference.

Independent claim 12 recites and apparatus comprising:

> pseudo skin; and
> a palpation module for enabling a user to palpate a pseudo vein, wherein;
> (a) said palpation module is disposed beneath said pseudo skin;
> (b) said palpation module generates a force that opposes downward motion of said pseudo vein; and
> (c) a magnitude of said force is substantially constant during application of said force.

As previously discussed, Kreitenberg does not disclose a pseudo vein that is pushed down; the pseudo vein disclosed in Kreitenberg is not pushed at all. Nor does Kreitenberg disclose a palpation module that generates a substantially constant force for opposing downward motion of the pseudo vein. Kreitenberg has no provision for generating any force in opposition to downward movement of a pseudo vein. But, even if the Office adopts an unreasonably and overly broad reading of the claim language, the intrinsic resistance offered by membrane (96) as it compresses is not substantially constant – it is rapidly increasing – such that the force that opposes downward movement would rapidly increase.

Therefore, claim 12 is not obvious in view of the combination of Kreitenberg and Cunningham.

Independent claim 21 includes some limitations that are the same as recited in claim 1, and, as consequence, claim 21 is allowable over the cited art on the same basis as claim 1.

Independent claim 27 recites:

> a pseudo vein; and
> an arrangement for generating a first force, wherein:
> (a) said first force opposes a second force;
> (b) said second force is applied to said pseudo vein by a user; and
> (c) said first force is magnetic.

Claim 27 is allowable on the same basis as claims 1 and 21. That is, the combination of Kreitenberg and Cunningham does not suggest generating a magnetic force that opposes a force that is applied to a pseudo vein by a user.

Thus, independent claims 1, 3, 12, 21, and 27 are allowable over the cited art. All claims dependent thereon are likewise allowable. Furthermore, the recitation of additional patentable features in the dependent claims provide a secondary basis for the patentability thereof.

B. Rejection of claims 2 and 20 under 35 USC §103 in view of Kreitenberg and Leight et al.

Claim 2 recites an apparatus comprsing:

> pseudo skin; and
> a palpation module for enabling a user to palpate a pseudo vein, wherein said palpation module is disposed beneath said pseudo skin, and further wherein said palpation module measures a change in position of said pseudo vein.

Neither Kreitenberg, Leight, nor the combination thereof, suggest what is recited in claim 2. In particular, neither of these reference teach a palpation module that enables a user to palpate a pseudo vein. Furthermore, neither of these references teach measuring a change in position of a pseudo vein. As previously discussed, Leight discloses that a pressure applied to a breast model during palpation can be sensed. But this is not a disclosure or suggestion to measure a change in position of a pseudo vein.

Thus, independent claim 2 is allowable over the cited art. Claim 20 is allowable based on its dependence on claim 2. Furthermore, the recitation of additional patentable features in claim 2 provides a secondary basis for its patentability.

Conclusion

It is believed that claims 1-34 now presented for examination are in condition for allowance. A notice to that effect is solicited.

Respectfully,
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